UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

UNITED STATES OF AMERICA,	)	Case No. 4:21-cr-00045-1
	)	
Plaintiff,	)	Judge J. Philip Calabrese
	)	
v.	)	Magistrate Judge
	)	Carmen E. Henderson
SAMIR WAHIB,	)	
	)	
Defendant.	)	
	)	

OPINION AND ORDER

Dr. Samir Wahib is charged with several offenses arising out of a purported scheme to defraud federal health care programs. Dr. Wahib moves to exclude the testimony of an expert the United States disclosed, Dr. John E. White, Jr. (ECF No. 49; ECF No. 50.) The Court held an evidentiary hearing and oral argument on this matter on August 12, 2022. For the reasons that follow, the Court **DENIES** Defendant's motion.

FACTUAL AND PROCEDURAL BACKGROUND

During the times relevant to this case, Dr. Samir Wahib, a doctor of osteopathic medicine and a board-certified obstetrician gynecologist, owned Women's OB/GYN Care, LLC, a women's health practice in Youngstown, Ohio. (ECF No. 26-3, PageID #136; ECF No. 27-2, PageID #667 & #671.) Previously, Dr. Wahib served as the chair of obstetrics and gynecology for Northside Hospital in Youngstown for more than a decade. (*See* ECF No. 26-19, PageID #249; ECF No. 27-10, PageID #866.)

In 2014, Dr. Wahib bought laboratory testing equipment for his office to detect sexually transmitted diseases, gonorrhea and chlamydia in particular. (ECF No. 26-3, PageID #136; ECF No. 27-2, PageID #674.) Before then, Dr. Wahib used a lab in Pennsylvania to test specimens. (ECF No. 26-3, PageID #136; ECF No. 27-2, PageID #674.) When Dr. Wahib began billing for laboratory services, CareSource, which insured many of his patients who participated in Ohio's Medicaid program, referred the matter to law enforcement for investigation. (ECF No. 26-3, PageID #136; ECF No. 27-2, PageID #672.)

A. Charges

On January 28, 2021, a grand jury indicted Dr. Wahib and co-defendant Dr. Joni Canby, who is also a doctor of osteopathic medicine and a specialist in obstetrics and gynecology. (ECF No. 1, ¶¶ 1, 2, PageID #1.) The United States charges Dr. Wahib, Dr. Canby, and Dr. Kapon (a family physician charged in a separate indictment in *United States v. Kapon*, No. 4:21-cr-64 (N.D. Ohio)) with conspiring to defraud and defrauding federal health care programs through a kickback scheme. (*Id.*, ¶ 3, PageID #1.)

According to the indictment, after obtaining laboratory equipment capable of testing for sexually transmitted infections, Dr. Wahib paid kickbacks to Dr. Canby and Dr. Kapon for providing specimens from their patients to test. (*Id.*, ¶¶ 19–21, PageID #6.) Then, Dr. Wahib submitted claims to the federal government for payment for the tests. (*Id.*, ¶¶ 20–21, PageID #6.) On the checks making the kickback payments to Dr. Canby and Dr. Kapon, the grand jury charges that

Dr. Wahib wrote "physician coverage" in the memo line to disguise the nature of the payments. (*Id.*, ¶¶ 24, 25, PageID #6.) Further, the indictment charges that the tests Dr. Wahib performed on his patients, and the tests he performed on specimens that Dr. Canby provided in exchange for kickback payments, were not medically necessary. (*Id.*, ¶¶ 39, 40, PageID #11.) Rather, Dr. Wahib submitted false and fraudulent claims to the federal government for reimbursement to which he knew he was not entitled. (*Id.*, ¶¶ 37, 41, PageID #11.) Regarding Dr. Wahib, the United States additionally alleges that he obstructed the criminal investigation when he instructed an employee to create false records to disguise kickbacks to Dr. Canby and Dr. Kapon and later, after learning that the employee had spoken to federal agents, warned the employee that if he "went down," the employee "would go down" too. (*Id.*, ¶¶ 54, 57, PageID #17–18.)

Dr. Wahib disputes the charges and advances innocent explanations for the facts on which the United States bases the indictment. For example, Dr. Wahib, Dr. Canby, and Dr. Kapon regularly covered shifts for one another, which, in Dr. Wahib's view, explains the notations on the checks that the United States finds suspicious. (*See* ECF No. 26-8, PageID #141; ECF No. 27-7, PageID #822–23 & #825.) As another example, Dr. Wahib maintains that he believed his payments to Dr. Canby and Dr. Kapon were lawful and that he relied on advice to that effect from, among others, the lab he previously used before purchasing his own testing equipment. (ECF No. 26-8, PageID #141; ECF No. 27-7, PageID #817 & #821.)

B. The Indictment

Against Dr. Wahib, the indictment charges the following offenses: (1) conspiracy to solicit, receive, offer and pay kickbacks in connection with a federal health care program (Count I); (2) offering or paying kickbacks in connection with a federal health care program (Counts II–V); (3) conspiracy to commit health care fraud (Count VIII); (4) health care fraud (Count IX); and (5) obstruction of a criminal investigation of federal health care offenses (Count XI). (ECF No. 1, ¶¶ 16–58, PageID #4–18.)

C. Proffered Expert Testimony

Under Rule 16 of the Federal Rules of Criminal Procedure, for any expert testimony the United States intends to use at trial, the government must disclose to the defendant a written summary of the testimony it intends to use during its case-in-chief, including the witness's opinions, the bases and reasons for those opinions, and the witness's qualifications. Fed. R. Crim. P. 16(a)(1)(G) (effective until Dec. 1, 2022).

The United States intends to call Dr. John E. White, Jr. to testify as an expert at trial regarding the medical necessity of the testing for sexually transmitted infections that Dr. Wahib conducted and submitted for reimbursement to federal health care programs. (ECF No. 55, PageID #2332.) Dr. White has practiced medicine in Ohio, specifically in the Tri-State Cincinnati area, for over thirty years with a specialization in obstetrics and gynecology. (ECF No. 26-24, PageID #255; ECF No. 27-15, PageID #881; ECF No. 55-1, PageID #2347; ECF No. 56,

PageID #2403.) In March 2021, Dr. White provided the United States with an analysis of the medical necessity of gonorrhea and chlamydia testing that Dr. Wahib and a co-defendant performed. (ECF No. 55-1, PageID #2347; ECF No. 56, PageID #2390.) Dr. White's March 2021 summary serves as the United States' disclosure under Rule 16.

However, the United States represented that it does *not* intend to have Dr. White testify about the applicable National Coverage Determination, which the Centers for Medicare and Medicaid Services uses to determine whether particular tests or services are medically necessary for purposes of reimbursement. (ECF No. 44, PageID #1459.) Nor does Dr. White's summary address that NCD. (*See* ECF No. 55-1; ECF No. 56.) With this context, Dr. White's opinions address the medical necessity in a clinical sense, without the regulatory overlay of how CMS determines whether to reimburse for particular tests—except to the extent that Dr. White opines that tests Dr. Wahib ordered were not medically necessary, which would make them improper for reimbursement in any event.

In his summary, Dr. White concludes that many of the tests Dr. Wahib performed were not medically necessary. (ECF No. 55-1, PageID #2347; ECF No. 56, PageID #2390.) To support this conclusion, Dr. White points specifically to the guidelines which the Centers for Disease Control and Prevention publish and the American College of Obstetrics and Gynecology has adopted—again, not CMS's applicable National Coverage Determination. (ECF No. 55-1, PageID #2347; ECF No. 56, PageID #2390.) According to his disclosure, Dr. White summarizes these

guidelines as recommending screening asymptomatic women for gonorrhea and chlamydia if they are under age 25 and sexually active or over age 25 with certain risk factors, which include: (a) new or multiple sexual partners; (b) a history of sexually transmitted infections; (c) exchanging sex for payment; (d) use of injection drugs; (e) having a sex partner who has multiple sex partners; (f) having a sex partner who has a sexually transmitted disease; or (g) pregnancy. (ECF No. 55-1, PageID #2347; ECF No. 56, PageID #2390–91.) Additionally, Dr. White opines that testing for sexually transmitted diseases is appropriate where the patient has a history that raises suspicion of an infection and the clinical signs and symptoms of an infection. (ECF No. 55-1, PageID #2347; ECF No. 56, PageID #2391.)

Under these governing standards, Dr. White reviewed the medical records of thirteen of Dr. Wahib's patients, comprising approximately twenty-seven visits where he ordered testing for gonorrhea and chlamydia. (ECF No. 55-1, PageID #2347; ECF No. 56, PageID #2391.) He also reviewed interviews agents with the Federal Bureau of Investigation conducted with some of these patients. (ECF No. 55-1, PageID #2347; ECF No. 56, PageID #2390.) Dr. White concluded that most of the gonorrhea and chlamydia tests Dr. Wahib ordered were not medically necessary. (ECF No. 55-1, PageID #2347; ECF No. 56, PageID #2392.)

In addition to this analysis, Dr. White created a summary chart for each of these thirteen patients of Dr. Wahib. (ECF No. 55-1, PageID #2347; ECF No. 56, PageID #2393–96.) For each patient and visit date, Dr. White noted whether gonorrhea and chlamydia testing was performed, the results of the tests, and

whether, in his opinion, the tests were medically necessary for either screening or diagnostic purposes under CDC guidelines and based on the patient's clinical presentation. (ECF No. 55-1, PageID #2347; ECF No. 56, PageID #2393–96.) Along with his determinations about the medical necessity of particular tests, Dr. White took handwritten notes compiling that information with some limited additional supporting information, such as the patient's sexual activity, marital status, and medical history. (USA Ex. 12.)

D. Motion to Exclude Dr. White's Testimony

On February 18, 2022, Defendant Wahib moved to exclude the opinions of Dr. White at trial pursuant to Rule 702. (ECF No. 49; ECF No. 50.) With his motion, Defendant submitted various supporting exhibits and a supplemental declaration from Dr. Kathryn Marko, a board-certified obstetrician and gynecologist who teaches at George Washington University School of Medicine and Health Sciences and practices in Maryland and Washington, D.C. (ECF No. 49-2; ECF No. 50-1.) As part of his motion, Defendant requested that the Court take judicial notice of various materials. (ECF No. 49-1.) In considering Defendant's motion, the Court considered these materials.

The Court conducted a hearing on Defendant's motion to exclude on August 12, 2022. During the hearing, the Court heard testimony from Dr. White and from Dr. Marko. Counsel for both parties were afforded the opportunity to examine each witness, then presented further arguments and answered questions from the Court.

That testimony and argument referenced many of the materials that were the subject of Defendant's request for judicial notice.

D.1. Dr. White's Testimony

Although Dr. White has worked on approximately seventy-five cases, primarily medical malpractice cases for defendants and one murder case in State court, he is not a professional witness. He began his testimony by discussing his education and experience, which includes practicing medicine since 1988 as an obstetrician and gynecologist in and around Cincinnati. Since 1990, he has been board certified in those specialties. Throughout his years in practice, Dr. White has served socio-economically diverse communities that required testing and screening for sexually transmitted diseases. He testified that he bases his opinions on this education, training, and experience and on his understanding of the relevant guidelines and literature that apply.

With respect to the summary of his opinions, Dr. White clarified that the summary itself and both the handwritten notes about each patient and the typed version of those notes were not exhaustive. Instead, they provided a summary of his work and his opinions. Similarly, he testified that the specific reference in his summary to the guidelines from the Centers for Disease Control and the American College of Obstetrics and Gynecology was not exhaustive or intended to exclude any publications that might be relevant to his opinions. In this respect, Dr. White testified that he is familiar with the appliable National Coverage Determination and included it as part of his work in this case. Indeed, his testimony on cross-

examination in particular demonstrated fluency with the applicable NCD. On cross-examination, Dr. White conceded that a physician is justified in following national guidelines to make clinical decisions.

As a general matter, cross-examination attempted to show that Dr. White inconsistently applied the various national guidelines and standards to his review of Dr. Wahib's patients and in formulating his opinions. With respect to the thirteen patients of Dr. Wahib he reviewed, Dr. White relied on his training and experience when analyzing the patient files and interviews. He did not dispute that nine had laboratory evidence of bacterial vaginosis, but he disputed that that fact alone made testing for gonorrhea or chlamydia clinically appropriate.

Counsel used the example of patient D.B. from Dr. White's notes to illustrate his methodology. Dr. White's notes show the following about D.B.:

Date of Service	GC/CHL Results	Med. Nec. per CDC Guidelines	Med. Nec. per Clinical History
2/15/2016	- / -	N	N (s/p hysterectomy,
7/21/2014	- / -	N	N married, monogramous
1/6/2011	Not Done	N	N per interview)

(ECF No. 55-1, PageID #2347; ECF No. 56, PageID #2393.) This summary chart shows that Dr. Wahib saw D.B. on three occasions. On two he ordered testing for gonorrhea (GC) and chlamydia (CHL) when D.B. was about 58 and 60 years old, respectively. On each occasion, Dr. White opines that the test was not medically necessary under the CDC Guidelines and based on the patient's clinical history, which he obtained from her interview with law enforcement. Dr. White noted that

D.B. had previously had a hysterectomy and was married and monogamous. According to her medical records, however, D.B. reported that she was separated in 2014 and divorced in 2016, which prompted Dr. White to explain that marital status matters less to him than being in a monogamous relationship.

Dr. White's handwritten notes about D.B. contain the additional information that she had positive laboratory test results in both 2014 and 2016 for bacterial vaginosis, though those results would not have been available when testing for gonorrhea and chlamydia was done. (USA Ex. 12.) Dr. White read his notes as "a positive Gardnerella test," not necessarily by definition bacterial vaginosis, which in Dr. White's opinion requires clinical correlation with the test result. Dr. White opined that, under the standard of care, women with hysterectomies are not typically screened for gonorrhea and chlamydia unless they are engaged in high-risk behaviors.

D.2. Dr. Marko's Testimony

In Dr. Marko's opinion, based on evidence-based guidelines from the United States Preventive Services Task Force, a volunteer panel of national experts, the standard of care requires screening for gonorrhea and chlamydia for patients at high-risk based on their individual and community risk factors. Dr. Marko testified that the USPSTF guidelines track the NCD for testing for sexually transmitted diseases and that if a physician follows the guidelines set forth in the NCD, then testing for sexually transmitted diseases is considered medically necessary and appropriate. She testified that the proper methodology for determining whether testing for

gonorrhea and chlamydia is medically necessary and appropriate involves reviewing each patient in detail and all relevant documentation, then applying the national guidelines and other literature to determine the medical necessity for testing or screening.

Where she practices in Washington, D.C., Dr. Marko testified that rates of infection are high, but lower than those in Youngstown, where Dr. Wahib practices. In her practice in Washington, D.C., she recommends screening for gonorrhea and chlamydia to every woman every year based solely on the community having high prevalence of these infections, without regard to individual risk factors. In this regard, Dr. Marko and Dr. White disagree: Dr. White testified that residence in a high-prevalence community does not necessarily make screening for sexually transmitted diseases medically appropriate.

Dr. Marko testified that Dr. White's methodology is fundamentally flawed because it did not reference or consistently apply these guidelines and other relevant literature that fall within the standard of care. In her view, he evinced a "disregard for all of the reasons we would perform screening and testing for gonorrhea and chlamydia," and his review of the NCD and other guidelines was incomplete as was their application. Similarly, regarding Dr. White's analysis of the thirteen patients of Dr. Wahib, Dr. Marko testified that Dr. White ignored many individual and community risk factors in his determination whether the screening was justified. With his "narrow lens," Dr. Marko believes that Dr. White missed relevant factors

that justify testing in those instances. Dr. Marko would have recommended gonorrhea and chlamydia testing for each of the thirteen patients at issue.

ANALYSIS

Before offering opinion testimony, Rule 702 requires that the witness be "qualified as an expert by knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Additionally, the Court must find that: (a) "the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue"; (b) "the testimony is based on sufficient facts or data"; (c) "the testimony is the product of reliable principles and methods"; and (d) "the expert has reliably applied the principles and methods to the facts of the case." *Id*. The relevancy prong of analysis under Rule 702 requires that an expert's opinions "fit" the facts of the case. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591 (1993).

Rule 702 "imposes a special obligation upon a trial judge to 'ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999) (quoting *Daubert*, 509 U.S. at 589). At bottom, this gatekeeping function ensures that expert evidence rests on a reliable foundation and is relevant to the task at hand. *Daubert*, 509 U.S. at 589, 597. But it does not require the Court to conclude that the "expert opinion is bulletproof." *United States v. Lang*, 717 F. App'x 523, 534 (6th Cir. 2017) (cleaned up). Although Rule 702 lists four prerequisites for expert testimony, the Supreme Court holds that the inquiry into reliability is ultimately flexible. *Kumho Tire*, 526 U.S. at 141. A district court has "considerable leeway in deciding in a particular case how to go about determining

whether particular expert testimony is reliable," including "discretionary authority . . . to avoid unnecessary 'reliability' proceedings" in appropriate cases. *Id.* at 152.

Beyond the formal requirements, one consideration courts factor into the analysis is whether the expert formed his opinions for purposes of the litigation or whether, instead, they are a natural outgrowth of the expert's independent work and research. *See Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1317 (9th Cir.1995) (following remand from the Supreme Court). Under Rule 702, what matters most is that any relevant evidence within the scope of the Rule "must be the 'product of reliable principles and methods' and must have been 'reliably applied' in the case." *United States v. Gissantaner*, 990 F.3d 457, 463 (6th Cir. 2021). The proponent of the expert testimony bears the burden of establishing its admissibility by a preponderance of the evidence. *Nelson v. Tennessee Gas Pipeline Co.*, 243 F.3d 244, 251 (6th Cir. 2001) (citing *Daubert*, 509 U.S. at 592 n.10).

In his motion, Defendant moves to exclude Dr. White's testimony as the product of incomplete and unreliable methods that he did not reliably apply to the facts of this case. Specifically, Defendant argues that Dr. White (1) ignored and contradicted the authoritative standards for sexually transmitted infection screening and diagnostic testing and (2) based his analysis on unreliable interview summaries that contradict the objective medical evidence. The Court addresses each of these specific arguments as part of discharging its broader gatekeeping obligations under Rule 702.

Before doing so, the Court exercises its discretion, based on the record and the nature of the expert testimony proffered, to determine reliability by evaluating whether a reasonable physician would consider testing or screening a patient for gonorrhea or chlamydia on a particular occasion medically appropriate or necessary and whether a reasonable physician would do so using the particular methodology Dr. White employed in this case. *See Kumho Tire*, 526 U.S. at 142, 152.

I. Qualifications

Defendant does not dispute Dr. White's qualifications to testify as an expert in this case. Indeed, Defendant concedes that experience alone may qualify a witness under Rule 702. (ECF No. 57, PageID #2420; ECF No. 58, PageID #2442.) At the hearing, Defendant affirmed that he is not questioning Dr. White's experience or credentials.

Having reviewed Dr. White's curriculum vita, the Court finds that Dr. White has sufficient qualifications to give the proffered opinions. Dr. White received his medical degree in 1984 from the University of Kentucky and is a board-certified specialist in obstetrics and gynecology. (ECF No. 55-1, PageID #2347; ECF No. 56, PageID #2403.) Further, he has practiced as an obstetrician gynecologist in Ohio for more than thirty years, and an integral part of his clinical practice includes ordering tests for sexually transmitted infections. (ECF No. 55-1, PageID #2347; ECF No. 56, PageID #2390.) Although Defendant does not challenge Dr. White's qualifications, in arguing that his opinions are not reliable Defendant notes that Dr. White lacks "specialty expertise" in sexually transmitted infection testing because he lists no

experience serving as a peer referee or on committees specific to sexually transmitted infection. (ECF No. 49, PageID #1535 n.13; ECF No. 50, PageID #2241 n.13.) But such facts do not detract from Dr. White's other qualifications to testify to the medical necessity of sexually transmitted infection testing, a subject well within his experience. The absence of such service does not disqualify Dr. White.

In short, Dr. White's education, board certification, and years of clinical experience demonstrate that he has sufficient qualifications to assess whether screening or testing for gonorrhea and chlamydia is medically necessary or appropriate for a particular patient and in particular facts and circumstances.

II. Reliability

To satisfy Rule 702, Dr. White's opinions must rest on a sufficient foundation, his principles and methods must be reliable, and he must reliably apply them to the facts of the case. In making these determinations, the Court primarily looks to the *Daubert* factors. *See* 509 U.S. at 593–94. But not every factor applies in each case. *See Surles ex rel. Johnson v. Greyhound Lines, Inc.*, 474 F.3d 288, 295 (6th Cir. 2007) (holding that the "gatekeeping inquiry is context-specific and must be tied to the facts of a particular case"). Further, while the *Daubert* factors might be relevant in some cases, in others "the relevant reliability concerns may focus upon personal knowledge or experience." *First Tenn. Bank N.A. v. Barreto*, 268 F.3d 319, 335 (6th Cir. 2001) (citing *Kumho Tire*, 526 U.S. at 153). Other considerations that might be relevant include whether experts propose "to testify about matters growing naturally and directly out of research they have conducted independent of the litigation," *Daubert*,

43 F.3d at 1317, and whether the expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field," *Kumho Tire*, 526 U.S. at 152.

Overall, the *Daubert* factors have little relevance in the present case, which involves expert testimony derived largely from Dr. White's clinical practice over more than thirty years as a board-certified obstetrician and gynecologist. Opinions formed in this manner do not easily lend themselves to scholarly review or to traditional scientific evaluation. *See First Tenn. Bank*, 268 F.3d at 335. However, the two additional factors identified in *Daubert*'s progeny—whether testimony grows naturally out of the expert's pre-litigation work and whether the expert brings his clinical practice to the courtroom or some different methodology—provide a useful measure for assessing reliability here and independently validating Dr. White's methodology. *See Kumho Tire*, 526 U.S. at 157.

II.A. Sufficiency of Facts and Data for Dr. White's Opinions

In preparing the summary of his opinions, Dr. White relied on his education, training, and experience in clinical practice as an obstetrician and gynecologist, his review of the medical records of thirteen specific patients, and the summaries of FBI interviews with them, known as 302s because the FBI memorializes interviews on Form FD-302 (*see* ECF No. 35-9; ECF No. 36-9). (ECF No. 55-1, PageID #2347; ECF No. 56, PageID #2390.) His opinions and work for this case grow naturally of out his clinical practice and experience, which he developed independently of this case or testimony in court more generally.

Defendant does not dispute that patient medical records are an appropriate basis for Dr. White's opinion. (*See* ECF No. 49; ECF No. 50.) However, Defendant objects to Dr. White's use of the interview summaries, prepared well after the tests at issue, for three reasons. (ECF No. 49, PageID #1532; ECF No. 50, PageID #2238.)

First, Defendant argues that these summaries were prepared in anticipation of this prosecution, making them "inherently unreliable." (ECF No. 49, PageID #1532; ECF No. 50, PageID #2238.) At some level, most or at least a great number of 302s are prepared in anticipation of prosecution. But that fact alone does not make their contents unreliable. Defendant relies on *United States v. Norris*, No. 1:05-CR-479-JTC/AJB, 2007 WL 9655845, at *13 (N.D. Ga. May 8, 2007), *report and recommendation adopted*, No. 1:05-CR-479-JTC, 2007 WL 9657880 (N.D. Ga. Oct. 3, 2007), in which the court determined that an expert's opinion was not based on sufficient facts or data. There, the expert witness relied wholly on law enforcement reports and interviews to opine that witnesses' behavior was consistent with a psychological condition, despite testifying that the normal evaluation techniques included interviews by trained interviewers and psychological tests. *Id.* Accordingly, this authority does not extend so far as to render all law enforcement reports and interviews inherently unreliable. Additionally, unlike in *Norris*, Dr. White did not rely solely on the interview summaries to form his conclusions or opine in an area where the standard of care required psychological testing or interviews by specially trained professionals.

Second, though the interview summaries in this case are likely inadmissible hearsay, experts may base their opinions on hearsay and other evidence otherwise inadmissible at trial. Fed. R. Evid. 703; *Kingsley Assocs., Inc. v. Del–Met, Inc.*, 918 F.2d 1277, 1286–87 (6th Cir.1990). Instead, the question under Rule 703 is whether the interview summaries are the type of material on which an expert in the field would rely. Defendant argues that they are not. Without question, in the strictest sense, Defendant is correct. No physician in practice relies on police reports or other interview summaries that law enforcement prepares. In the context of a criminal prosecution, however, Dr. Wahib's patients are not available for Dr. White to interview or perform his own medical evaluation. The formalities of courtroom litigation make the interview summaries a reasonable substitute for the history a physician would otherwise take from a patient in practice. Therefore, a reasonable physician, given the circumstances, would similarly rely on the interview summaries.

Defendant points to inconsistencies between the interview summaries and the medical records as evidence of their unreliability and insufficiency in providing a basis for expert testimony. (ECF No. 49, PageID #1532–33; ECF No. 50, PageID #2238–39.) Because the interview summaries reflect what the patients self-reported about their medical histories to law enforcement agents, in some cases years after the fact, discrepancies between the content of the interviews and the medical records are unavoidable. Additionally, the agents might not have accurately summarized the interviews in some material respect. In this respect, however, the interview summaries are no different than the medical records themselves, which

depend on the quality of the patient as an historian and the transcriber's skill in accurately recording that information. The interview summaries add the additional complicating factor of being removed in time from the underlying events at issue. But that marginal wrinkle does not make them inherently unreliable or qualitatively change the analysis that applies to the medical records themselves in any material respect for purposes of Rules 702 or 703.

Third, Defendant relies on two cases in which the medical experts relied totally on medical histories that counsel for the plaintiffs prepared and provided to them. *See In re TMI Litig.*, 193 F.3d 613, 698 (3d Cir. 1999), *amended*, 199 F.3d 158 (3d Cir. 2000); *In re Silica Prods. Liab. Litig.*, 398 F. Supp. 2d 563, 675 (S.D. Tex. 2005). In contrast, Dr. White relied only in part on the summaries of interviews with some patients and also reviewed and relied on the patients' medical records. Further, Dr. Marko recognized that the appropriate methodology involves considering as much information as is available. She testified that it would not be appropriate to rely on the interview reports without confirmation in the medical records. In this respect, her opinion confirms the unreliability and unreasonableness of relying on summaries that potentially interested persons prepared, as in *In re TMI Litigation* and *In re Silica Products Liability Litigation*, and provides independent confirmation that cross-referencing such summaries with medical records does not present a similar methodological deficiency here.

For these reasons, the Court determines that Dr. White reasonably relied on the interview summaries in conjunction with the medical records as an available

substitute for conducting his own interview with the patients at issue because, on the facts and circumstances of this case, they are not otherwise available to him. Further, based on the record before the Court, including the testimony of Dr. Marko, the Court determines that a reasonable physician would use these same materials in forming his or her opinions for purposes of litigation. Based on his experience and review of the medical records as well as the interview summaries, the Court determines that Dr. White's opinions are based on "sufficient facts or data."

II.B. Reliability of Dr. White's Principles and Methods

The primary basis for Defendant's motion relates to the guidelines on which Dr. White relied to assess the medical necessity of Dr. Wahib's testing for gonorrhea and chlamydia. In his Rule 16 disclosure, Dr. White relied on guidelines that the Centers for Disease Control and Prevention published for testing women for gonorrhea and chlamydia. (ECF No. 55, PageID #2336; ECF No. 56, PageID #2390.) By pointing to these guidelines, Dr. White identifies an objective basis by which to test his opinions. Defendant argues that Dr. White's methodology is not reliable because it disregards the guidance contained in NCD 210.10, the National Coverage Determination for Screening for Sexually Transmitted Infections issued by the Centers for Medicare and Medicaid Services. (ECF No. 49, PageID #1513; ECF No. 50, PageID #2219.) Based on the Court's review of the record, however, the CDC Guidelines and the NCD sufficiently overlap and provide a sufficient basis—one that a reasonable physician would use—for Dr. White's opinions.

Throughout this discussion, two distinct terms might get confused or conflated, so the Court takes a moment here to clarify them, though it might (regrettably) use them interchangeably. Screening tests are those involving a certain segment of the population based on certain risks and criteria unrelated to clinical signs or symptoms. Diagnostic testing responds to a patient's presentation with clinical signs and symptoms that warrant further investigation to rule in or rule out a particular diagnosis.

II.B.1. Screening

Based on NCD 210.10, Defendant argues that Dr. White should have applied the individual and community social risk factors listed in the NCD to assess Dr. Wahib's screening decisions. (ECF No. 49, PageID #1514; ECF No. 50, PageID #2220.) Defendant argues both that Dr. White failed to apply this risk-factor analysis and that, to the extent the CDC guidelines overlap with or embody the NCD, he did not reliably apply it. (ECF No. 49, PageID #1514; ECF No. 50, PageID #2220.)

As to community social risk factors, NCD 210.10 states that, in addition to individual risk factors, "community social factors such as high prevalence of [sexually transmitted infections] in the community populations should be considered in determining high/increased risk for chlamydia, gonorrhea, syphilis." (ECF No. 55-3, PageID #2364.) And the guidelines from the American College of Obstetrics and Gynecology and Ohio Medicaid are in accord. (ECF No. 26-32, PageID #487; ECF No. 26-34, PageID #498.) Dr. White did not mention the community rate of sexually transmitted infections in his summary. However, the United States provided

Dr. White with literature related to the prevalence of sexually transmitted infections in the area in which Dr. Wahib practiced. (ECF No. 55, PageID #2339.) Additionally, the area in which Dr. White practices has a higher prevalence of sexually transmitted infections than the area where Dr. Wahib does. (*Id.*) Dr. White testified at the hearing that residence in an area with high sexually transmitted infection rates is relevant to screening patients for these infections. (*See also id.*, PageID #2339–40.) Because the record makes clear that Dr. White is aware of the community prevalence factor and its import through his clinical practice, though not expressly mentioned in the Rule 16 summary of his opinions, the Court determines that Dr. White's mere failure to mention community prevalence in his summary does not make his opinions unreliable.

Defendant points to four additional social risk factors which his expert, Dr. Marko, based on her review of multiple authorities, opines are relevant to screening: "(i) Black race; (ii) Hispanic ethnicity; (iii) developmentally disabled status; and (iv) Medicaid beneficiary status." (ECF No. 49, PageID #1515; ECF No. 50, PageID #2221; ECF No. 49-2, PageID #1554; ECF No. 50, PageID #2252.) Because these factors do not appear in NCD 210.10, the Court does not see how Dr. White's omission of these factors from the summary of his opinions renders his methodology (or even his conclusions) unreliable, especially given Defendant's emphasis on NCD 210.10 as the controlling standard. (*See* ECF No. 49, PageID #1513–15; ECF No. 50, PageID #2219–21.)

Turning to individual risk factors, NCD 210.10 lists eight. (ECF No. 26-38, PageID #492.) Though Defendant contends that Dr. White ignored the individual risk factors, the United States shows that he applied at least five of the ones listed in NCD 210.10. (ECF No. 55, PageID #2338.) Specifically, Defendant argues that Dr. White failed to consider the individual risk factor of "using barrier protection inconsistently." (ECF No. 49, PageID #1519–20; ECF No. 50, PageID #2225–26.) The United States contends that this factor applies only outside of mutually monogamous relationships and that Dr. White impliedly considered it when he noted which patients were married and monogamous. (ECF No. 55, PageID #2339.) Further, at the hearing, Dr. White agreed that inconsistent use of barrier protection outside of monogamous relationships is relevant to determining the medical necessity of screening for gonorrhea and chlamydia, though it has less importance relative to the other factors. Because Dr. White mentioned and applied most if not all of the individual risk factors enumerated in NCD 210.10, the Court determines that he conducted a sufficient analysis of them. Therefore, his methodology is reasonably reliable under Rule 702.

Finally, Defendant argues that Dr. White incorrectly applied the risk factor of pregnancy. (ECF No. 49, PageID #1520–22; ECF No. 50, PageID #2226–28.) In support, Defendant points to Dr. White's statement that "[t]esting is required in the state of Ohio once during pregnancy." (ECF No. 55-1, PageID #2347; ECF No. 56, PageID #2391.) However, Dr. White's statement about what is required under Ohio law does not bear on the medical necessity standard that he applied. Under NCD

210.10, whether additional testing during pregnancy is necessary depends on "if high-risk sexual behavior has occurred since the initial screening test." (ECF No. 55-3, PageID #2363.) Although Dr. White determined that additional screening after the first screening for one pregnant patient was not medically necessary, this conclusion does not necessarily contradict NCD 210.10. Accordingly, a reasonable physician could have reached the same conclusion, and Dr. White did not unreliably apply this risk factor.

II.B.2. Diagnostic Testing

Tuning to diagnostic testing for sexually transmitted infections, Defendant contends that Dr. White's methodology is unreliable because he failed to consider certain clinical signs and symptoms. (ECF No. 49, PageID #1522; ECF No. 50, PageID #2228.) Dr. White's summary states that diagnostic testing is appropriate where a patient has clinical symptoms and a medical history that puts her at risk for sexually transmitted infections: "Briefly, the symptoms and signs of a gonorrhea or chlamydia infection are: an abnormal vaginal discharge that appears purulent . . . or mucopurulent . . . or numerous white blood cells on a microscopic exam of the vaginal discharge, accompanied by pelvic pain." (ECF No. 55-1, PageID #2347; ECF No. 56, PageID #2391.)

Defendant argues that Dr. White omitted other signs or symptoms of gonorrhea and chlamydia infections that warrant diagnostic testing. (ECF No. 49, PageID #1523–25; ECF No. 50, PageID #2229–31.) For example, Defendant contends that Dr. White should have considered vaginitis, dyspareunia, threatened pre-term

labor, and unexplained proximal urethral inflammatory polyps. (ECF No. 49, PageID #1524; ECF No. 50, PageID #2230.) On comparison to Defendant's extensive list of signs and symptoms of gonorrhea and chlamydia, Dr. White's brief summary did not exhaustively list the signs and symptoms potentially relevant to diagnostic testing. Dr. White testified that he considers the criteria for diagnostic testing as part of a patient's clinical presentation when assessing whether testing is appropriate. (*See also* ECF No. 55, PageID #2340.) Broad consideration of clinical presentation subsumes consideration of the specific signs and symptoms Defendant raises. Therefore, the Court determines that Dr. White's methodology has sufficient reliability for purposes of Rule 702.

II.B.3. Other Arguments

Defendant argues Dr. White's methodology is unreliable for four other reasons, which the Court addresses in turn.

First, the United States argues that some of the thirteen patients Dr. White evaluated were on the "older side," supporting the conclusions that Dr. Wahib's testing in these instances was not medically necessary. (ECF No. 49, PageID #1526; ECF No. 50, PageID #2232.) Defendant objects that a patient's older age and her history of prior testing should not affect whether a particular test is medically necessary. (ECF No. 49, PageID #1526; ECF No. 50, PageID #2232.) In particular, Defendant maintains that the only mention of age in the NCD relates to a sexually active woman under age 24. (ECF No. 49, PageID #1526; ECF No. 50, PageID #2232.) Dr. White's testimony at the hearing made clear that, when determining medical

necessity, he assumed women, regardless of age, remained sexually active. Therefore, age alone does not provide a basis for Dr. White's conclusions, which rest on a sufficiently reliable methodology that a reasonable physician would use.

In this respect, Defendant's objection also goes to Dr. White's notations of hysterectomy status because, according to several authoritative sources, hysterectomy status does not bear on whether sexually transmitted infection testing is medically necessary. (ECF No. 49, PageID #1527; ECF No. 50, PageID #2233.) Dr. White noted the hysterectomy status of three patients in his summary chart reflecting his individual analysis of each patient, suggesting it was a factor he considered when assessing medical necessity. (ECF No. 55-1, PageID #2347; ECF No. 56, PageID #2392 & #2395.) At the hearing, Dr. White testified that he considers hysterectomy status relevant to whether testing is medically necessary because a woman who has had a hysterectomy is at a lower health risk from sexually transmitted infections. Because Dr. White offers this opinion based on his clinical practice and experience, and a reasonable physician could reach the same conclusion, the Court finds that this opinion rests on a sufficiently reliable foundation. Defendant's criticism of Dr. White's opinion on this issue presents a matter for cross-examination, the opinions of Dr. Marko, or both.

Second, Defendant objects to the argument of the United States that Dr. Wahib's failure to order a test for a particular patient in the past (before he acquired the testing equipment) bears on the medical necessity of tests in the future (after he did). (ECF No. 49, PageID #1527–29; ECF No. 50, PageID #2233–35.)

Defendant argues that such an argument impermissibly expresses an opinion as to Dr. Wahib's mental state. (ECF No. 49, PageID #1528; ECF No. 50, PageID #2234.) Moreover, Defendant contends, relying on the opinion of Dr. Marko, that failure to test in the past would actually *increase* the clinical justification of later testing. (ECF No. 49, PageID #1528; ECF No. 50, PageID #2234.) But Dr. White offers no opinion on Dr. Wahib's mental state, and the temporal relationship between the tests Dr. Wahib ordered and the testing equipment he bought rests on medical necessity in particular circumstances. Because Dr. White's conclusion rests on the evaluation of the medical necessity for screening or testing in each particular instance, the argument the United States makes about testing history does not does alter the reliability of Dr. White's principles or methods.

Third, Defendant objects to Dr. White's statement in the summary of his opinions that testing for sexually transmitted infections is "deemed to be not medically necessary" if the provider fails to "document the pertinent history, (including a sexual history) symptoms and signs that make the diagnostic testing medically necessary." (ECF No. 55-1, PageID #2347; ECF No. 56, PageID #2391; *see also* ECF No. 49, PageID #1530; ECF No. 50, PageID #2236.) Defendant notes that NCD 210.10 does not require documentation, but states only that the "medical record should be a reflection of the service provided." (ECF No. 49, PageID #1530; ECF No. 50, PageID #2236.) At the hearing, Dr. White expanded on this opinion by explaining that a physician has a responsibility to document appropriately the patient history or physical exam findings that provide the rationale for providing any

service for which the physician will bill the insurance provider. Without appropriate documentation, according to Dr. White, the insurance provider will deem the service to be medically unnecessary. Although an expert on billing and reimbursement practices, rather than a physician, might be better or additionally suited to provide this opinion, the Court understands Dr. White to be speaking from the perspective of a professional service provider who bears some responsibility for providing the front-line documentation or justification for the services provided. In any event, Defendant does not point to any part of Dr. White's analysis where he determined a test was not medically necessary because of a lack of documentation, and the United States represents that it will not elicit testimony from Dr. White as an expert in billing. Accordingly, Dr. White's statement on this point does not affect the reliability of his analysis.

Fourth, Defendant argues in his reply brief that Dr. White applied a legally erroneous definition of medical necessity in his report, constituting an error in methodology that renders his testimony unreliable. (ECF No. 57, PageID #2414–17; ECF No. 58, PageID #2436–39.) Defendant did not raise this argument in his initial brief. (*See* ECF No. 49; ECF No. 50.) It is well established that a party forfeits arguments made for the first time in reply. *See Sanborn v. Parker*, 629 F.3d 554, 579 (6th Cir. 2010) (citing *American Trim, L.L.C. v. Oracle Corp.*, 383 F.3d 462, 477 (6th Cir. 2004)). Therefore, the Court declines to consider this argument.

* * *

For these reasons, the Court determines that Dr. White used a reliable methodology, based on his education, training, and experience in clinical practice as an obstetrician gynecologist, to assess whether the instances of Dr. Wahib's screening and diagnostic testing for sexually transmitted infections were medically necessary and in formulating his opinions for this case.

II.C. Reliability of Dr. White's Conclusions

Even if Dr. White's methods are reliable, however, the Court must also ensure that his conclusions reasonably follow from his methods. *See General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("[C]onclusions and methodology are not entirely distinct from one another."). An otherwise qualified expert may not simply connect his conclusions to the underlying data and record with his own assertions. *Id.* Such *ipse dixit* is not proper opinion evidence. Nor may an expert stray too far from the bases supporting his testimony. At times, that analytical gap might be too great for an expert to testify reliably. *Id.* In short, an expert must reasonably apply his principles and methods to the facts of the case. Fed. R. Evid. 702(d).

As already discussed, Dr. White relied on sufficient facts and data and his analysis was reasonably consistent with relevant professional guidelines, including the standard contained in NCD 210.10. Based on the testimony of Dr. White, Dr. Marko, and the record on Defendant's motion, the Court determines that Dr. White has not simply asserted conclusions based on his authority or expertise. Instead, he grounds his opinions in the medical records and other information available to him as a reasonable physician would. Nor does he stray too far from that

foundation to offer speculative testimony disguised as expert opinion. His conclusions represent his reasoned medical judgment. To be sure, expert opinions based on training and experience might heighten the risk of *ipse dixit* or an impermissible analytical gap. But Dr. White has not fallen into those traps.

Defendant argues that Dr. White has not reliably applied his expertise or the applicable guidelines in forming his conclusions. At the hearing, Defendant focused this argument on Dr. White's analysis of two tests conducted on patient D.B. as a representative of the thirteen patients he specifically reviewed. In Dr. White's opinion, neither was medically necessary. (ECF No. 55-1, PageID #2347; ECF No. 56, PageID #2393.) Dr. White noted that D.B. had undergone a hysterectomy and was "married, monogamous per interview." (ECF No. 55-1, PageID #2347; ECF No. 56, PageID #2393.) At the hearing, Dr. White clarified that he understood D.B. was married and monogamous from the summary of the interview conducted by law enforcement. However, contemporaneous medical records reflect that D.B. reported she was separated at the time of the first test and single and divorced at the time of the second. At the second test, she identified her emergency contact as her domestic partner. Notwithstanding these discrepancies between the medical records and the summary of D.B.'s interview with investigators, Dr. White explained that the material consideration in forming his opinion is whether the patient is monogamous, not whether she is married.

In this respect, Dr. White has a sufficient basis for his opinions regarding the medical necessity for D.B.'s tests. At this stage, both the medical records and

interview summaries are hearsay, which Rule 703 allows an expert to consider in reaching his conclusions. The interview summary, medical records, or both might not be accurate. But as things stand before trial, these materials provide a sufficient basis for Dr. White's opinions, he explained the reasons for his conclusions, and did not stray too far from the underlying data, his expertise, or the relevant guidelines. Because Defendant argued at the hearing that substantially similar flaws infect Dr. White's analysis of each of the thirteen patients he reviewed, the Court need not consider each separately. In short, the record shows that Dr. White's opinions are sufficiently reliable for a jury to consider them.

III. Fit

An expert opinion is only relevant if it is "sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." *Daubert*, 509 U.S. at 591. In other words, expert testimony must fit the facts of the case. *United States v. LeBlanc*, 45 Fed. App'x 393, 400 (6th Cir. 2002). Dr. White's testimony relates to the issues involving medical necessity for screening and testing at issue in the case and will aid the jury in its assessment of the evidence and its deliberations. Defendant disagrees and argues that Dr. White's testimony has no relevance for substantially the same reasons that he contends it is unreliable: failure to apply the correct standard; failure to consider certain risk factors, signs, and symptoms; reliance on irrelevant factors; and the assumption of facts that conflict with medical records. (ECF No. 49, PageID #1537–38; ECF No. 50, PageID #2243–44.) The Court has addressed Defendant's arguments on these points in the context of reliability and

determined that Dr. White's opinion has a sufficient foundation and results from a reliable methodology that he applies reliably to the facts of the case. Whether Dr. White's opinion helps the United States prove the elements of the offenses charged beyond a reasonable doubt presents a different question. Because Dr. White's testimony "will assist the trier of fact to understand the evidence," however, it fits the facts of the case and will help the jury evaluate the evidence and resolve the factual disputes between the parties. *See In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 528–29 (6th Cir. 2008).

IV. Final Considerations

In deciding Defendant's motion, the Court addresses three last points this record presents.

IV.A. Additional Gatekeeping Factors

The record shows that Dr. White comes into court with over thirty years of clinical experience in obstetrics and gynecology and that his practice has long included ordering the types of diagnostic and screening tests for gonorrhea and chlamydia at issue. In this respect, his opinions grow naturally out of his pre-litigation work. In other words, he did not become an expert for the purpose of offering the opinions at issue. *See Kumho Tire*, 526 U.S. at 157. These considerations support the reliability of and provide some independent validation for Dr. White's principles, methods, and conclusions.

IV.B. Weight of the Evidence

Often, courts simply see an expert with impressive qualifications or experience and conclude that any challenge to that witness's opinions or methodology goes to the weight of the evidence, not its reliability or admissibility. Just as often, where courts invoke this maxim, they have failed to exercise their gatekeeping obligation or, perhaps, not even understood it. In analyzing the record and Defendant's motion, the Court has not taken such an approach. Instead, at every step of the analysis under Rule 702, the Court has endeavored to ensure that its gatekeeping determination does not simply devolve into punting to the jury.

IV.C. Dr. White's Rule 16 Disclosure

Effective December 1, 2022, an amendment to Rule 16 will take effect, bringing the disclosure obligations for criminal cases more closely in line with the current practice in civil cases under Rule 26(a)(2). *See* Fed. R. Crim. P. 16 (effective Dec. 1, 2022) advisory committee's note to 2022 amendment. Under the amendment, Dr. White's disclosure would fail to provide adequate notice to Defendant of the opinions he expects to offer at trial and the bases for them. Among other things, Dr. White's disclosure made no mention of NDC 210.10, and that failure would foreclose him from offering opinions on it. Although the Court would prefer broader or more robust disclosure, Rule 16 presently requires less , the United States discharged its obligations under Rule 16 regarding the testimony of Dr. White.

CONCLUSION

In the exercise of its gatekeeping obligation, the Court finds that Dr. White is qualified to offer his opinions, which rest on a sufficient basis, are the product of reliable methods, and reflect a reliable application of those methods. In short, subject to the constraints of this criminal prosecution, Dr. White applies the same rigor in this matter as he does in his practice, and a reasonable physician would employ the same or substantially similar methodology in considering whether testing or screening a patient for sexually transmitted infections on a particular occasion is medically appropriate or necessary. For all the foregoing reasons, the Court **DENIES** Defendant's motion to exclude Dr. White's testimony.

SO ORDERED.

Dated: October 21, 2022

J. Philip Calabrese
United States District Judge
Northern District of Ohio